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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CB/1/22/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

January 20, 1999

WARNING LETTER

Dr. Walter Mosher, Ph.D., President
Precision Dynamics Corporation
13880 Del Sur Street
San Fernando, CA 91340

KAN #99-009

Dear Dr. Mosher:

We are writing to you because on December 1 - 3, 1998, an FDA Investigator from this office conducted an inspection at your facility located at 814 K Street, Belleville, Kansas, which revealed a serious regulatory problem involving your sterile devices such as the urine collection leg bag and the pediatric urine collector.

Under the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to demonstrate through documentation that the pediatric urine collector sterile package system has been validated.

- Failure to provide documented validation that the package sealing machines used for the pediatric urine collector can consistently produce closed seals, knowing that the machines have ongoing residual heating problems.

- Failure to document required sterile package integrity testing for each lot of devices labeled as sterile.

- Failure to conduct sterile package integrity testing using actual finished product of sterile medical devices.

- Failure to produce sterilization processing records for lot No. 225 of sterile leg bags which were released for shipment on 11-16-98.

- Failure to review all device history records prior to the release of devices.

- Failure to have a quality audit procedure that allows for auditing the firm's quality system.

- Failure to conduct an investigation of the bioburden testing for urine collection leg bags when CFU's to numerous to count (TNTC) were found, and to determine any detrimental impact this would have on the device.

- Failure to have in place a document control system which will assure that the most current version of operation procedures are available to employees.

- Failure to include product labeling in the device history record for each lot of device manufactured.

This letter is not intended to be an all-inclusive list of deficiencies at your Belleville, Kansas, facility. At the conclusion of the inspection Form FDA 483 was issued to Mr. Curtis C. Crawford, Director of Operations. This is a list of the QSR deviations made by the Investigator during the inspection. A copy is enclosed for your information. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

We have received and reviewed two letters dated December 9 and 23, 1998, from Mr.Curtis C. Crawford, Director of Operations, which represents responses to the Form FDA 483 observations. These letters were reviewed prior to the issuance of this letter.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking, in addition to the December 9 and 23 letters, to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Clarence R. Pendleton, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Clarence R. Pendleton at (913) 752-2103.

Sincerely,

Garrett D. Salmon (for)
W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Curtis C. Crawford, Director
of Operations
Precision Dynamics Corporation
814 K Street
Belleville, KS 66935